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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,294	09/29/2003	Thomas L. Cantor	532212001900	5531

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EXAMINER

CHEU, CHANGHWA J

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/674,294

Applicant(s)

CANTOR ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 16-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/2/2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-15 in the reply filed on 6/30/2006 is acknowledged.
2. Claims 1-15 are under examination. Claims 16-24 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 8, "wherein the shelf-life" lacks antecedent basis.

With respect to claim 8, the "shelf-life" is vague and indefinite. It is not sure whether applicant means "half-life" referring to the activity of the peptide.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
6. Claims 1-3, 6-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Gao et al. (J. Bone Mineral Res (2001) Vol. 16, page 605- applicant submitted IDS filed on 1/2/2005).

Art Unit: 1641

Gao et al. teach a parathyroid hormone (PTH) assay control. The assay comprises a whole PTH component having amino acid 1-84 of PTH, and a PTH fragment having amino acid 7-84 of PTH which falls within the recited range, i.e. spanning position 2 through 33 of PTH of its N-terminal, and C-terminal spanning from 35 through position of 84 of PTH, where Gao et al. teach storing the PTH in lyophilized form, e.g. protein matrix base (See page 606, right column, Materials and Methods- Chemicals and Reagents).

With respect to claim 2 and 14-15, Gao et al. teach comparing the binding assay of IRMA and conventional Nichols assay by mixing the whole PTH component with the PTH fragment in a predetermined ratio (See Figure 2).

With respect to claim 3, Gao et al. using synthetic method to generate the PTH components. Supra.

With respect to claims 6-8, Gao et al. teach using lyophilized form for storage of the PTH components to prolong storage life of the PTH peptides. Supra.

With respect to claims 9-10, Gao et al. established that there is no cross-reactivity of whole PTH with the 7-84 PTH fragment by detecting binding of these two peptides in different ration (See Figure 2).

With respect to claims 11 and 13, Tthe recitation of “instructions” is not afforded patentable weight because the recited “instructions” are not functionally related to the underlying kit, but merely teach a new use for an existing product. In re Ngai, 70 USPQ2d 1862 (CAFC 2004).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1641

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-6, 11-15 rejected under 35 U.S.C. 103(a) as being unpatentable over Bouillon et al. (Clin. Chem. (1990) Vol. 36, page 271) in view of Holthuis et al. (US 5496801).

Bouillon et al. teach a parathyroid hormone (PTH) assay control. The assay comprises a whole PTH component having amino acid 1-84 of PTH, and a PTH fragment having amino acid 23-84 of PTH which falls within the recited range, i.e. spanning position 2 through 33 of PTH of its N-terminal, and C-terminal spanning from 35 through position of 84 of PTH, (See page 271, right column, Materials and Methods-Reagents).

However, Bouillon et al. do not explicitly teach using protein matrix base to prolong the storage of the PTH peptides.

Wang et al. teach using inactivated human serum albumin as protein matrix base to increase storage life of PTH (Col. 1, line 35-55).

Art Unit: 1641

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bouillon et al. with the lyophilizer as taught by Holthuis et al. in order to increase the storage life of the PTH peptides for subsequent analysis.

With respect to claim 2 and 14-15, Bouillon et al. teach comparing interfering effects of PTH fragments by mixing the whole PTH component with the PTH fragment in a predetermined ratio, e.g. excess of 1000 fold molar ratio (See page 273, right column, second paragraph).

With respect to claim 3, Buillon et al. using synthetic method to generate the PTH components. Supra.

With respect to claims 4-5, Bouillon et al. teach purifying PTH from natural sources, such as human hPTH by chromatography (See page 272, left column, second paragraph). Although Bouillon et al. teach isolate and purify hPTH (52-84), which does not fall within the recited amino acid residue range, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Bouillon et al. to isolate 7-84 or 23-84 PTH since using chromatograph of isolating peptide of interest is a routine practice in the field, and a matter of time/cost consideration comparing chemical synthesis of peptide.

With respect to claims 11 and 13, Tthe recitation of “instructions” is not afforded patentable weight because the recited “instructions” are not functionally related to the underlying kit, but merely teach a new use for an existing product. In re Ngai, 70 USPQ2d 1862 (CAFC 2004).

Conclusion

10. No claim is allowed.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

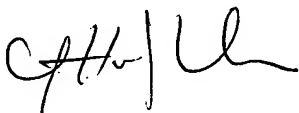
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu

Examiner

Art Unit 1641



August 22 2006



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